IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. MSN LABORATORIES PVT. LTD., MSN PHARMACEUTICALS INC. AND MSN LIFE SCIENCES PVT. LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants MSN Laboratories Private Ltd. ("MSN Labs"), MSN Pharmaceuticals Inc. ("MSN Inc.") and MSN Life Sciences Pvt. Ltd. ("MSN Life") (collectively, "MSN"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 ("the RE'059 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to MSN's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the RE'059 patent.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, MSN Labs is a corporation organized under the laws of India and its principal place of business is located at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 18 Telangana, India.

6. Upon information and belief, MSN Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 20 Duke Road, Piscataway, NJ 08854. Upon information and belief, MSN Inc. is a wholly owned subsidiary of MSN Labs. http://msnpi.com/ (accessed Oct. 20, 2020).

7. Upon information and belief, MSN Life is a corporation organized under the laws of India and its principal place of business is located at Sy No - 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India. Upon information and belief, MSN Life is a wholly owned subsidiary of MSN Labs.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over MSN Labs. Upon information and belief, MSN Labs is in the business of manufacturing, marketing, importing and selling pharmaceutical

drug products, including generic drug products. Upon information and belief, MSN Labs directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, MSN Labs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of MSN's generic products.

10. Upon information and belief, MSN Labs admits it is "a research-based pharmaceutical company" with "more than 40,000,000 customers across 65 countries globally," including the United States. http://www.msnlabs.com/who-we-are.html (accessed Oct. 20, 2020).

11. Upon information and belief, MSN Labs is engaged in the development and/or manufacturing of MSN's generic products. Upon information and belief, MSN Labs admits it has "375 US … DMFs." http://www.msnlabs.com/our-achievements.html (accessed Oct. 20, 2020). Upon information and belief, MSN Labs admits one of its future objectives is to "actively file DMFs & Dossiers/ANDAs." http://msnlabs.com/our-future.html (accessed Oct. 23, 2019). Upon information and belief, MSN Labs applied for one or more patent applications directed to the preparation of brexpiprazole. *See, e.g.*, International Publication No. WO 2018/087775 (titled "Process for the preparation of 7-{4-[4-(1-benzothiophen-4-ya)piprazin-1-yl]butoxy}quinoline-2(1H)-one," and designating the United States for the national phase) and U.S. Publication No. 2019/0359606 (titled "Process for the preparation of 7-{4-[4-(1-benzothiophen-4-ya)piprazin-1-yl]butoxy}quinoline-2(1H)-one").

12. This Court has personal jurisdiction over MSN Inc. Upon information and belief, MSN Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MSN Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States

and in this judicial district. Upon information and belief, MSN Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of MSN's generic products.

13. Upon information and belief, MSN Inc. is the U.S. agent for MSN Labs. Upon information and belief, MSN Inc. admits it "is a state-of-the-art finished dosage manufacturing facility" and "is replete with Corporate Offices, Research and Development area, Laboratories, and Manufacturing Units." http://msnpi.com/ (accessed Oct. 20, 2020).

14. This Court has personal jurisdiction over MSN Life. Upon information and belief, MSN Life is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MSN Life directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, MSN Life purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of MSN's generic products.

15. Upon information and belief, MSN Life "is a research-based pharmaceutical company," has "an integrated R&D Center for Contract Research And Manufacturing Services" and "serves clients worldwide." https://www.bloomberg.com/profile/company/1603294D:IN (MSN Life Bloomberg Profile, accessed Oct. 20, 2020).

16. Upon information and belief, MSN Life is the holder of FDA Drug Master File No. 32142 for brexpiprazole.

17. Upon information and belief, MSN Labs, MSN Inc. and MSN Life hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products

throughout the United States, including in this judicial district.

18. Upon information and belief, MSN Labs admits it is vertically integrated. http://msnlabs.com/news.html (accessed Oct. 22, 2019); *see also* http://www.msnlabs.com/api.html (accessed Oct. 20, 2020). Upon information and belief, MSN Labs admits that its portfolio includes 100 ANDAs and alleges that "[t]oday, [it is] #1 in the world in active US DMF filings." http://www.msnlabs.com/api.html (accessed Oct. 20, 2020).

19. Upon information and belief, MSN Inc. admits it "is a fully owned subsidiary of the MSN group of companies" and "develops and manufacture [*sic*] products for MSN group as well as specialized [*sic*] in contract development and manufacturing of high-quality generic pharmaceutical products." http://msnpi.com/ (accessed Oct. 20, 2020). Upon information and belief, MSN Inc. further admits it offers "[m]anufacturing services of complex pharmaceutical products with backward integrated APIs to global markets." *Id.* Upon information and belief, MSN Labs admits MSN Inc. is a US Office and part of the "MSN group of companies." *Id.*; http://msnlabs.com/contact.html (accessed Oct. 20, 2020).

20. Upon information and belief, MSN Labs admits MSN Life is one of its API Facilities and part of the "MSN Group of Companies." http://www.msnlabs.com/contact.html (accessed Oct. 18, 2019); *see also* http://msnlabs.com/contact.html (accessed Oct. 20, 2020).

21. MSN's ANDA filing regarding the RE'059 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts MSN's intent to market and sell MSN's generic products in this judicial district.

22. MSN has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the

United States. Upon information and belief, MSN intends to direct sales of its generic drugs in this judicial district, among other places, once MSN receives the requested FDA approval to market its generic products. Upon information and belief, MSN will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

23. Upon information and belief, MSN has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213740.

24. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because MSN Labs and MSN Life are incorporated in India and may be sued in any judicial district.

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because MSN Inc. is incorporated in the state of Delaware.

FACTUAL BACKGROUND

The NDA

26. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms ("REXULTI® Tablets").

27. The FDA approved NDA No. 205422 on July 10, 2015.

28. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patent In Suit

29. The United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 7,888,362 ("the '362 patent") on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders."

30. The PTO reissued the '362 patent as the RE'059 patent on June 23, 2020. A true and correct copy of the RE'059 patent is attached as Exhibit A.

31. As the reissue of the '362 patent, Otsuka is the owner of the RE'059 patent through assignment as recorded by the PTO for the '362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

32. Pursuant to 35 U.S.C. § 251, the RE'059 patent issued for the unexpired term of the '362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

33. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059, which was granted on October 6, 2020. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

34. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

35. Upon information and belief, MSN filed ANDA No. 213740 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("MSN's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

36. Otsuka received a letter sent by MSN, dated September 12, 2019, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213740 ("MSN's September 12, 2019, First Notice Letter") pursuant to § 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)B)(i)-(iv) and 21 C.F.R. § 314.95. MSN's September 12, 2019, First Notice Letter notified Otsuka that MSN had filed ANDA No. 213740, seeking approval to engage in the commercial manufacture, use or sale of MSN's generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent") and 10,307,419 ("the '419 patent").

37. In response to MSN's September 12, 2019, First Notice Letter, Plaintiffs previously filed a separate action in this Court against MSN for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. MSN Laboratories Pvt. Ltd., et al.*, C.A. No. 19-cv-2009-LPS.

38. On June 23, 2020, the PTO reissued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

39. Upon information and belief, ANDA No. 213740 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the RE'059 patent are invalid, unenforceable, and/or would not be infringed by MSN's generic products.

40. Otsuka received a second notice letter sent by MSN, dated September 9, 2020, purporting to be a "Notice of Certification" for ANDA No. 213740 ("MSN's September 9, 2020, Second Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug & Cosmetic Act and 21 C.F.R. § 314.95. MSN's September 9, 2020, Second Notice Letter notified Otsuka that MSN had filed ANDA No. 213740, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of MSN's generic products before the expiration of the RE'059 patent.

41. Plaintiffs commenced this action within 45 days of receiving MSN's September 9, 2020, Second Notice Letter.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

42. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

43. Upon information and belief, MSN filed ANDA No. 213740 seeking approval to manufacture, use, import, offer to sell and/or sell MSN's generic products in the United States before the expiration of the RE'059 patent.

44. Upon information and belief, MSN filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

45. Upon information and belief, in its ANDA No. 213740, MSN has represented to the FDA that MSN's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

46. MSN has actual knowledge of Otsuka's RE'059 patent, as evidenced by MSN's September 9, 2020, Second Notice Letter.

47. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), MSN has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213740, seeking approval to commercially manufacture, use, import, offer to sell or sell MSN's generic products before the expiration date of the RE'059 patent.

48. Upon information and belief, if ANDA No. 213740 is approved, MSN intends to and will offer to sell, sell and/or import in the United States MSN's generic products.

49. Upon information and belief, if ANDA No. 213740 is approved, MSN will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing MSN's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213740 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

50. Upon information and belief, MSN's actions relating to MSN's ANDA No. 213740 complained of herein were done by and for the benefit of MSN.

51. Plaintiffs will be irreparably harmed by MSN's infringing activities unless this Court enjoins those activities.

52. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that MSN has infringed at least one claim of the RE'059 patent through MSN's submission of ANDA No. 213740 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell MSN's generic products in the United States before the expiration of the RE'059 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that MSN's making, using, offering to sell, selling or importing of MSN's generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of MSN's generic products shall be no earlier than the expiration date of the RE'059 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining MSN and all persons acting in concert with MSN from commercially manufacturing, using, offering for sale or selling MSN's generic products within the United States, or importing MSN's generic products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining MSN and all persons acting in concert with MSN from seeking, obtaining or maintaining approval of the ANDA until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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